Pneumococcal conjugate vaccine failure segment from Immunization Update satellite broadcast, August 15, 2002

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Our next vaccine brief concerns pneumococcal conjugate vaccine, or PCV. In February 2000, the Food and Drug Administration approved the first pneumococcal conjugate vaccine, a seven-valent vaccine with the brand name Prevnar. Shortly thereafter, the ACIP and the American Academy of Pediatrics recommended the use of PCV for all children 2 through 23 months of age, and children 24 through 59 months of age with increased risk for pneumococcal disease.

Since PCV was licensed for use, there have been reports of invasive pneumococcal disease among infants and children who had received at least one dose of the vaccine. But cases of invasive disease following vaccination are to be expected. In the clinical trials that led to licensure, vaccine efficacy was estimated to be 97 percent for invasive disease with pneumococcal serotypes included in the vaccine, and 89 percent for all serotypes. The reason that some vaccinated children appear not to be protected, particularly when the infection is caused by a serotype included in the vaccine, is not known.

It's important that we understand more about why some children fail to be protected following vaccination with PCV. We need your help to accomplish this. CDC's Respiratory Diseases Branch, in the National Center for Infectious Diseases, has developed a system to monitor and investigate this and other pneumococcal conjugate vaccine issues.

The system is intended to determine the serotype of these invasive pneumococcal isolates, determine conditions in the child that may increase the risk of severe pneumococcal disease, and monitor for vaccine lots that may be less effective. This tracking system is consistent with the Council for State and Territorial Epidemiologists recommendation that invasive pneumococcal disease in children less than 5 years old be placed under national surveillance.

There are four conditions that must be met in order for a case to be eligible for reporting. First, the child is less than 5 years old. Second, the child has an invasive pneumococcal infection. An invasive infection is defined as isolation of Streptococcus pneumoniae from a normally sterile site, such as

cerebrospinal fluid, blood, joint fluid, or pericardial fluid. Third, there is a pneumococcal isolate available for serotyping. And, the fourth condition is the child has a history of at least one dose of PCV. If all four conditions are met, a PCV failure case report form should be completed and sent along with the isolate and a CDC lab report form to your State Health Department. It's important to fill out the case report form as completely as possible, including the vaccination history.

Your State Health Department will send the isolate, case report form, and laboratory form to the Streptococcus laboratory at CDC. Cases of suspected PCV failure may also be reported to the Vaccine Adverse Events Reporting System, or VAERS. Reporting to VAERS about these cases is not required unless there is a clinically significant adverse event after vaccination with PCV.

The PCV Failure Case Report and an instruction sheet are available on the NIP website. The instruction sheet will provide information on how to complete the case report and send the isolate. You will also find a link to the CSTE position statement on our website. We will include these websites on the resource page for this broadcast.